REMARKS

Claims 46-55 are pending and under consideration in view of Applicants' election made on May 1, 2008 in response to the Restriction Requirement issued on April 4, 2008. Claims 46-50 and 52-55 have been amended herein to further clarify the subject matter being claimed. Claim 51 has been cancelled herein without prejudice. Claims 1-45 have been withdrawn herein from consideration as being drawn to a non-elected invention and have also been cancelled without prejudice. No new matter or new issue is being introduced by these amendments. Reconsideration of the present application and allowance of pending claims 46-50 and 52-55 are respectfully requested in view of the amendments and following remarks.

I. Rejections under 35 U.S.C. §112, second paragraph

Claims 46-55 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite or incomplete for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. More particularly, the Office Action alleged that claims 46-55 are incomplete because the compositions must consist of at least two components. Furthermore, the Office Action alleged that the term "essentially" in claim 54 renders the claim indefinite because the term "essentially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicants respectfully traverse the rejection.

With respect to the rejection for alleged incomplete composition claims, Applicants respectfully point out that claim 51 has been cancelled without prejudice, and claims 46-50 and 52-55, as amended herewith, claim an isolated neural progenitor cell derived from a human embryonic stem cell, rather than a composition comprising the isolated progenitor cell. Accordingly, the amendments to these claims render the rejection moot.

With respect to the term "essentially" in claim 54, Applicants respectfully point out that the specification does define the term "essentially" as follows:

> "Essentially' means that a *de minimus* or reduced amount of a component, such as LIF, may be present that does not eliminate the improved bioactive neural cell culturing capacity of the medium or environment (paragraph [051], lines 1-8).

The definition of "essentially" is defined generally and applies not only to LIF by way of an example, but also to other excipients including "serum". Thus, it is clear that one of ordinary skill in the art would understand that "essentially serum free" means that a *de minimus* or reduced amount of serum may be present that does not eliminate the improved bioactive neural cell culturing capacity of the medium.

Accordingly, because claims 46-55 are complete and definite, and the term "essentially" in claim 54 is clearly defined in light of the specification, Applicants respectfully request the rejection of claims 46-55 under 35 U.S.C. §112, second paragraph, be withdrawn.

IV. **Rejections under 35 U.S.C. §102**

A. Claims 46-55 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 5,968,829 to Carpenter (1999) (IDS Ref. #8, "Carpenter '829 patent"). More particularly, the Office Action alleged that Carpenter '829 patent teaches compositions comprising "nestin"-positive neural stem/progenitor cells in serum-free DMEM/F-12 medium comprising the low molecular weight component, insulin (which comprises proline), and the neural inducing factors, EGF, bFGF, PDGF, NGF & LIF, which were also proliferated up to 130 cell divisions and 90 days in culture, as relates to claims 46, 47-50, 52 & 54. Also, Carpenter '829 patent allegedly anticipates the claimed invention because the MEDII medium defined in claim 55 only consists of at least one of the components (a)-(f). In addition, because the claimed composition in claim 46 does not require MEDII medium, itself, as a component, claim 53 is allegedly thus anticipated because HepG2 conditioned medium is not claimed as part of the composition. Applicants respectfully traverse the rejection.

It is respectfully pointed out that claim 46 has been amended to further clarify the invention by explicitly reciting that the claimed composition comprises an isolated nestin-positive neural progenitor cell derived *in vitro* from a human embryonic stem cell (hESC), wherein the neural progenitor cell has been stabilized by contact with MEDII conditioned

medium for greater than 2 passages, and wherein the neural progenitor cell can differentiate into more than one type of further differentiated neural cell.

In contrast, the Carpenter '829 patent describes "neural cells" derived from human fetal forebrain (hFBr), and not derived *in vitro* from human embryonic stem cells, as in amended claim 46. FIG. 1 in the Carpenter '829 patent "shows a representation of spheres of proliferating 9FBr human neural stem cells (passage 6) derived from human forebrain tissue" (*emphasis added*). Moreover, it is the human fetal forebrain cells which were "passaged every 6-21 days depending upon the mitogens used and the seeding density (*see* Example 2 of Carpenter '829 patent, col. 8, line 18 to col. 9, line 3). That is, the 9FBr human neural stem cells were not passaged. In fact, Carpenter '829 patent "conclude[s] from these data that [the 9FBr] cells will follow reproducible differentiation patterns irrespective of passage number or culture age [of the hFBr cells]" (*see* Example 3 of Carpenter '829 patent, col. 10, lines 23-25).

Therefore, because Carpenter '829 patent does not teach each and every limitation of the claimed invention, Carpenter '829 patent does not anticipate claims 46-55. Accordingly, Applicants respectfully request that the rejection of claims 46-55 under 35 U.S.C. §102(e) as being anticipated by Carpenter '829 patent be withdrawn.

B. Claims 46-55 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by WO 0151611 to Bresagen Limited/Rathjen et al. (IDS Ref. #14, "the Rathjen publication"). More particularly, the Office Action alleged that the Rathjen publication teaches compositions comprising "nestin"-positive neuroectoderm/EPL embryoid bodies/neural stem/progenitor cells in serum-free HepG2-conditioned MEDII medium, in which WO99/53021 (IDS Ref. #18) is incorporated by reference and states that "EPL cell morphology could be maintained with extended culture of greater than 40 passages, or 100 days. Accordingly, the Office Action concluded that the process limitation of claims 47-50 are anticipated, as well as claim 51 because contact with MEDII does not reasonably change the nestin positive neural cells of Rathjen even after "one year", and if the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art

product was made by a different process (as it relates to claim 51). Applicants respectfully traverse the rejection.

As discussed above, the claim 46 has been amended to further clarify the invention by explicitly reciting that the claimed composition comprises an isolated nestin-positive neural progenitor cell derived *in vitro* from a human embryonic stem cell (hESC). In contrast, the Rathjen publication describes nestin-positive neural ectoderm/EPL embryoid bodies (EBs) in serum-free HepG2 conditioned MEDII that are derived from mouse embryonic stem cells.

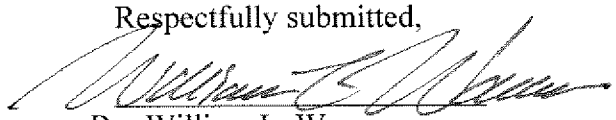
Therefore, because the Rathjen publication does not teach each and every limitation of the claimed invention, the Rathjen publication does not anticipate claims 46-55. Accordingly, Applicants respectfully request that the rejection of claims 46-55 under 35 U.S.C. §102(e) as being anticipated by the Rathjen publication be withdrawn.

CONCLUSION

Applicants submit that the present application, as amended, is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The foregoing is submitted as a full and complete response to the Office Action mailed July 14, 2008. No fees are believed due at this time. However, please charge any fees that may be due, or credit any overpayment, to Deposit Account 19-5029 (Ref. No.: 18377-0061).

In addition, if there are any issues that can be resolved by a telephone conference or an Examiner's amendment, the Examiner is invited and encouraged to call the undersigned attorney at (404) 853-8000.

Respectfully submitted,



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